

**Louisiana Medicaid**  
**Onasemnogene abeparvovec-xioi (Zolgensma®)**

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for onasemnogene abeparvovec-xioi (Zolgensma®).

*Onasemnogene abeparvovec-xioi (Zolgensma®) has a **Black Box Warning**. Please refer to prescribing information for details.*

**Approval criteria for onasemnogene abeparvovec-xioi (Zolgensma®) requests**

- The recipient has reached full-term gestational age (defined as 39 weeks 0 days) on the date of the request (documentation showing gestational age at birth [in weeks and days] must be provided with the request); **AND**
- The recipient is less than 2 years of age on the date of the request; **AND**
- Onasemnogene abeparvovec-xioi (Zolgensma®) is prescribed by, or the request states that onasemnogene abeparvovec-xioi (Zolgensma®) is being prescribed in consultation with, a neurologist experienced in the treatment of SMA; **AND**
- The following are true and **stated on the request**:
  - The recipient has a diagnosis of spinal muscular atrophy (SMA) with bi-allelic mutations in the *survival motor neuron 1 (SMN1)* gene; **AND**
  - The recipient **DOES NOT HAVE advanced SMA** (e.g., complete paralysis of limbs, permanent ventilator dependence); **AND**
  - The recipient **has never received a dose** of onasemnogene abeparvovec-xioi (Zolgensma®); **AND**
  - The recipient has a baseline anti-AAV9 antibody titer  $\leq 1:50$ , measured using an enzyme-linked immunosorbent assay (ELISA) [**date and results must be written on the request**]; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, prior treatment requirements (such as systemic corticosteroids) and required storage and handling procedures; **AND**
  - Where feasible, the recipient's vaccination schedule has been adjusted to accommodate concomitant corticosteroid administration prior to and following onasemnogene abeparvovec-xioi (Zolgensma®) infusion (seasonal RSV prophylaxis is not precluded); **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of onasemnogene abeparvovec-xioi (Zolgensma®).

**Duration of Approval: 1 month**

**Reference**

Zolgensma (onasemnogene abeparvovec-xioi) [package insert]. Bannockburn, IL: AveXis, Inc.; 2019. Retrieved from [https://www.avexis.com/content/pdf/prescribing\\_information.pdf](https://www.avexis.com/content/pdf/prescribing_information.pdf)